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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/674,279

09/29/2003

Wolfgang Hartung

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

05/08/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/674,279	Applicant(s) HARTUNG, WOLFGANG	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-11,17,18,21,22,25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3,6-11,17,18,21,22,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. DE 102 45 852.9.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 2, 2006 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-36-11, 17-18, 21-22 and 25-26 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-2, 6-7, 17-18 and 21-22 and 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "associated as a sensor" in the claims 6-7, 17-18 and 21-22 and 25 is unclear id the electrode is itself a sensor or is in connection is another sensor.

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Claims 1-2, 10 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2, 10 and 26 recite the broad recitation "at high frequency", and the claim also recites "30 and 100 ms" which is the narrower statement of the range/limitation.

Regarding claims 2, 10 and 26, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 1-2, 8, 10 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. Regarding claims 1-2, 8, 10 and 26, the word "means" is preceded by the word(s) "of said wall electrode", "of said floating", "of at least one floating electrode" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

As to claim 1, it is unclear if the circuit has this "first mode" as recited in claim 1, or another element. Also, it is unclear if the circuit is delivering the stimulation of another element.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 6-11, 17-18, 21-22 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt (US 5,403,355). Alt discloses an implantable medical device with a wall electrode, at least one floating electrode and circuitry to switch from a first mode to a second mode. The floating electrode 72 "bipolar electrodes integrated in the lead so as to be positioned in the right atrium when the lead is properly implanted"(col. 15, lines 18-20). The wall electrode is the electrode tip 70, which "is

positioned, when the lead is properly implanted, to be in direct contact with the myocardium in the right ventricle, and provide ventricular ECG status"(col. 15, lines 5-8) and thus effects atrial myocardium stimulation.

As to claims 2, 10 and 26, the examiner considers the floating atrial electrode to dispense stimulation therapy when the system detects high frequency irregularities.

"In this case, however, the microprocessor 29-1 also has the benefit of the atrial ECG status information derived from the atrial bipolar electrode for use in the evaluation, independent of the ventricular ECG status. Since this information from the atrium indicates the presence of AT, the evaluation performed by the microprocessor may be programmed in those circumstances to attribute the VT to primary atrial origin. Thus, the response is substantially immediate selection by the microprocessor of a therapy regimen to terminate the atrial tachycardia or fibrillation, which led to the VT. An appropriate therapy, then, where atrial fibrillation is determined by evaluation of the sense signals to be the primary cause of a secondary VT, is to deliver low energy shocks, such as in a range from 0.25 to 1.0 joule, from device 25 to the myocardium of the atrial chambers, via one of the two poles of the bipolar sensing electrode(s) 72 disposed in the right atrium and the external patch or the vena cava counter-electrode"(col. 15-16, lines 66-68 and lines 1-16).

As disclosed by Alt, during the detection of AT and/or VT the "immediate selection by the microprocessor of a therapy regimen" indicates the switch from a sensing mode, or first mode, to a stimulation mode, or a second mode. Converting from a sensing mode, that would "effect atrial myocardium stimulation", to a therapy mode

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that directly affects myocardial stimulation via shocks sent to the sensing electrode 72, which is the floating electrode. The wall sensor and floating sensor provides information relating to atrial dysrhythmias. The mode switching occurs when the microprocessor detects dysrhythmias and converts the system from sensing to stimulating.

As to claims 3 and 11, the electrodes 71-73 are floating electrodes as depicted in figure 6. Also, electrodes "71, 72, 73 and so forth on this lead are used for atrial and ventricular cardioversion or defibrillation and for bipolar sensing or conventional bipolar pacing according to device functions and patient requirements at any given time. For example, electrode surface 71 is a coil counter-electrode arranged to be positioned in the right ventricle for ventricular defibrillation, while electrode 73 is of similar configuration adapted to be positioned in or near the vena cava, when the lead is seated"(col. 15, lines 9-17). Therefore, Alt discloses the incorporation of two or more floating electrodes.

As to claims 6-7, 17-18, 21-22 and 25, both the wall and floating electrodes function as sensors in determining atrial dysrhythmias. The floating electrode is a sensor placed in the atrium, while the wall sensor is placed in the right ventricle, but "is associated as a sensor with the circuit for perceiving atrial signals" since the sensor associates with the microprocessor. The microprocessor is the circuit for perceiving atrial signals and the circuit for switching between modes.

As to claim 9, Alt discloses in col. 11, lines 40-59, the "tachycardia recognition rate of 150 bpm" which "is about 150 Hz or higher" as claimed by the Applicant.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Alyssa M Alter
Examiner
Art Unit 3762



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